For the Use of a Registered Medical Practitioner Only.

1. GENERIC NAME AND BRAND NAME

Lactulose Enema 20%w/v
DUPHALAC® RAPID

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Lactulose Solution I.P.
Equivalent to Lactulose 200 mg
Sodium Benzoate I.P. 3 mg
(as Preservative)
Purified Water I.P. q.s.

3. DOSAGE FORM AND STRENGTH

Refer section 1 & 2.

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

For constipation & hepatic encephalopathy.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

Directions for use:
Step 1: Before administration, wear fresh gloves and position patient in right lateral position.
Step 2: Observe for any rectal pathology.
Step 3: Remove the cap from the tube and open the clamp.
Step 4: Insert 2 to 3 Inches of tube in the anus. Roll the pouch to squeeze all content into the rectum.
Step 5: Remove enema tube slowly and carefully after administration is completed.
Step 6: Ask patient to retain Duphalac Rapid for 30-60 minutes.

4.3. CONTRAINDICATION

- Hypersensitivity to the active substance or to any of the ingredients.
- Galactosaemia.
- Gastrointestinal obstruction, digestive perforation or risk of digestive perforation

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Consultation of a physician is advised in case of:
- Painful abdominal symptoms of undetermined cause before the treatment is started
- Insufficient therapeutic effect after several days.

Lactulose should be administered with care to patients who are intolerant to lactose.

Chronic use of unadjusted doses and misuse can lead to diarrhea and disturbance of the electrolyte balance.

This product contains lactose, galactose and small amounts of fructose. Therefore, patients with rare hereditary problems of galactose or fructose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

When administered as a retention enema, due to the strong cathartic effect, fecal incontinence, bedsoiling, and peri-anal irritation due to the acidic stool can be expected. The hydration status of the patient should be observed carefully.

This product contains sulphite from the route of production.

4.5. DRUG INTERACTIONS

No interaction studies have been performed.

4.6. USE IN SPECIAL POPULATION (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

No effects during pregnancy are anticipated, since systemic exposure to lactulose is negligible.
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to lactulose is negligible.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Lactulose has no or negligible influence on the ability to drive and use of machines.

4.8. UNDESIRABLE EFFECTS

Summary of the safety profile:

If high doses [normally only associated with hepatic encephalopathy (HE)] are used for an extended period of time, the patient may experience an electrolyte imbalance due to diarrhea.

Hypersensitivity reactions mainly limited to the skin have been observed and identified as potential adverse reactions during post approval use. Because these reactions were reported spontaneously from a population of uncertain size, it is not possible to reliably estimate their frequency.

Tabulated list of adverse reactions

The following undesirable effects have been experienced with the below indicated frequencies in lactulose-treated patients in placebo-controlled clinical trials [very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000)] or have been reported spontaneously during post approval use [frequency not known (a precise frequency cannot be estimated from the available data)].

MedDRA SOC	Frequency Category			
	Very Common	Common	Uncommon	Frequency not known
Immune system disorders				Hypersensitivity
Gastrointestinal disorders	Diarrhea	Flatulence, abdominal pain, nausea, vomiting		

Skin and subcutaneous tissue disorders				Rash, pruritus, urticaria, erythema
Investigations			Electrolyte imbalance due to diarrhea	

Paediatric population
The safety profile in children is expected to be similar as in adults.

4.9. OVERDOSE

If the dose is too high, the following may occur:
Symptom: diarrhea and abdominal pain.
Treatment: cessation of treatment or dose reduction. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5. PHARMACOLOGICAL PROPERTIES

5.1. MECHANISM OF ACTION AND PHARMACODYNAMIC PROPERTIES

In the colon lactulose is broken down by colonic bacteria into low-molecular organic acids. These acids lead to a lowering of pH in the colonic lumen and via an osmotic effect to an increase of the volume of the colonic contents. These effects stimulate the peristalsis of the colon and return the consistency of the stools. The constipation is cleared, and the physiological rhythm of the colon is reinstated.

In hepatic encephalopathy (HE), the effect has been attributed to suppression of proteolytic bacteria by an increase of acidophilic bacteria (e.g. lactobacillus), trapping of ammonia in the ionic form by acidification of the colonic contents, catharsis due to the low pH in the colon as well as an osmotic effect, and alteration of the bacterial nitrogen metabolism by stimulating the bacteria to utilize ammonia for bacterial protein synthesis.

Within this context, however, it should be realized that hyperammonemia alone cannot explain the neuropsychiatric manifestations of HE. The ammonia however might serve as a model compound for other nitrogenous substances.

Lactulose as a prebiotic substance strengthens the growth of health promoting bacteria, like Bifidobacterium and Lactobacillus, whereas potentially pathogenic bacteria, like Clostridium and Escherichia coli may be suppressed.

This may lead to a more favorable balance of the intestinal flora.

5.2. PHARMACOKINETICS PROPERTIES

Lactulose is poorly absorbed after oral administration, and it reaches the colon unchanged. There it is metabolised by the colonic bacterial flora. Metabolism is complete at doses up to 25-50 g or 40-75 ml; at higher dosages, a proportion may be excreted unchanged.

6. NON-CLINICAL PROPERTIES

6.1. ANIMAL TOXICOLOGY AND PHARMACOLOGY

The results of acute, sub-chronic and chronic toxicity studies in various species indicate that the compound has very low toxicity. The effects observed, appear to be more related to the effect of bulk in the gastrointestinal tract than to a more specific toxic activity.

In reproduction and teratology experiments in rabbits, rats or mice no adverse effects were found.

7. DESCRIPTION

Clear, light yellow to brownish yellow color solution.

8. PHARMACEUTICAL PARTICULARS

8.1. INCOMPATIBILITIES

Not applicable.

8.2. SHELF-LIFE

Refer pack.

8.3. PACKAGING INFORMATION

Refer pack.

8.4. STORAGE AND HANDLING INSTRUCTIONS

Refer pack.

9. PATIENT COUNSELLING INFORMATION

a) Appropriate treatment

Each ml of Duphalac® Rapid contains Lactulose Solution I.P. equivalent to Lactulose 200mg.

Directions for use:
Step 1: Before administration, wear fresh gloves and position patient in right lateral position.
Step 2: Observe for any rectal pathology.
Step 3: Remove the cap from the tube and open the clamp.
Step 4: Insert 2 to 3 Inches of tube in the anus. Roll the pouch to squeeze all content into the rectum.
Step 5: Remove enema tube slowly and carefully after administration is completed.
Step 6: Ask patient to retain Duphalac Rapid for 30-60 minutes.

Do's and Don'ts for administration:
Remove the cap.
Remove the clamp.
Roll the pouch.
Never cut the tube.

b) Interactions

No interaction studies have been performed.

c) Warning and precautions

Consultation of a physician is advised in case of insufficient therapeutic effect after several days. Lactulose should be administered with care to patients who are intolerant to lactose. Persistent loose stools.
Advise patients to stop Duphalac® Rapid and contact their healthcare provider if they experience persistent loose stools.

10. DETAILS OF MANUFACTURER

Refer Pack for manufacturer details.

MARKETED BY:

Abbott India Limited
Angel Space, Lifestyle, Bldg. No. D-4,
Gala No. 4 to 10 & 14 to 20 Ground floor,
107 to 110 & 117 to 120 1st floor,
207 to 210 & 217 to 220 2nd floor,
Pimplas, Dist. Thane, Bhiwandi-421 302,
Maharashtra, India.

11. DETAILS OF LICENSE NO. WITH DATE

MNB/07/617 dated 26-July-2024

12. DATE OF REVISION

Version 1.0 dated 5-Mar-25

For product complaints and queries please write to
webmasterindia@abbott.com

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Source:
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Looze enema SmPC.